

## § 32.56

(c) An application for a license or for amendment of a license may include a description of procedures proposed as alternatives to those prescribed by paragraph (b) of this section, and proposed criteria for acceptance under those procedures. The Commission will approve the proposed alternative procedures if the applicant demonstrates that:

(1) They will consider defective any sampled device which has a leakage rate exceeding 0.1 percent of the original quantity of tritium or promethium 147 in any 24-hour period; and

(2) The operating characteristic curve or confidence interval estimate for the alternative procedures provides a Lot Tolerance Percent Defective of 5.0 percent at the consumer's risk of 0.10.

(d) No person licensed under § 32.53 shall transfer to persons generally licensed under § 31.7 of this chapter:

(1) Any luminous safety device which has been tested and found defective under the criteria and procedures specified in this section, unless the defective units have been repaired or reworked and have then met the tests set out in paragraph (b) of this section; or

(2) Any inspection lot which has been rejected as a result of the procedures in § 32.110 or alternative procedures in paragraph (c) of this section, unless the defective units have been sorted and removed or have been repaired or reworked and have then met the tests set out in paragraph (b) of this section.

[30 FR 8192, June 26, 1965, as amended at 39 FR 22129, June 20, 1974; 39 FR 26397, July 19, 1974]

## § 32.56 Same: Material transfer reports.

Each person licensed under § 32.53 shall file an annual report with the Director of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, which must state the total quantity of tritium or promethium-147 transferred to persons generally licensed under § 31.7 of this chapter. The report must identify each general licensee by name, state the kinds and numbers of luminous devices transferred, and specify the quantity of tritium or promethium-147 in each kind of

## 10 CFR Ch. I (1-1-03 Edition)

device. Each report must cover the year ending June 30 and must be filed within thirty (30) days thereafter.

[60 FR 3737, Jan. 19, 1995]

## § 32.57 Calibration or reference sources containing americium-241: Requirements for license to manufacture or initially transfer.

An application for a specific license to manufacture or initially transfer calibration or reference sources containing americium-241, for distribution to persons generally licensed under § 31.8 of this chapter, will be approved if:

(a) The applicant satisfies the general requirements of § 30.33 of this chapter;

(b) The applicant submits sufficient information regarding each type of calibration or reference source pertinent to evaluation of the potential radiation exposure, including:

(1) Chemical and physical form and maximum quantity of americium 241 in the source;

(2) Details of construction and design;

(3) Details of the method of incorporation and binding of the americium-241 in the source;

(4) Procedures for and results of prototype testing of sources, which are designed to contain more than 0.005 microcurie of americium-241, to demonstrate that the americium-241 contained in each source will not be released or be removed from the source under normal conditions of use;

(5) Details of quality control procedures to be followed in manufacture of the source;

(6) Description of labeling to be affixed to the source or the storage container for the source;

(7) Any additional information, including experimental studies and tests, required by the Commission to facilitate a determination of the safety of the source.

(c) Each source will contain no more than 5 microcuries of americium-241.

(d) The Commission determines, with respect to any type of source containing more than 0.005 microcurie of americium-241, that:

(1) The method of incorporation and binding of the americium-241 in the